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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA, CLARK COUNTY

THE VACCINE CENTER LLC, d/b/a THE VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability company,

Plaintiff,

vs.

GLAXOSMITHKLINE LLC, a Delaware limited liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH DISTRICT; DOES I-X and ROE CORPORATIONS I-X, inclusive,

Defendants.

Case No. 2:12-cv-01849-JCM-NJK

PLAINTIFF'S CONSOLIDATED OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

(Oral Argument Requested)

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

A. Own Use

In *Abbott Laboratories v. Portland Retail Druggists Association, Inc.*, 425 U.S. 1 (1976), the Supreme Court ruled that the "own use" exemption to Robinson-Patman antitrust liability under the Nonprofit Institutions Act ("NPIA"), 15 U.S.C. § 13c, applies only to its "patients" and does not apply to a hospital's sale of pharmaceutical drugs to "walk-in" customers. Here, defendant Southern Nevada Health District ("SNHD") claims that the "own use" exemption should apply to episodic walk-in customers, as well as the employees of casinos and other businesses that SNHD actively solicits. Just as the Supreme Court observed regarding comparable antitrust conduct, SNHD is acting like a "commercially advantaged" business that is "devastatingly positioned with respect to competing commercial" businesses that supply vaccines. *Abbott*, 425 U.S. at 17-18. The only way that Defendants can prevail in their "own use" exemption argument is if this Court ignores or overrules *Abbott.* Thus, the "own use" exemption argument fails, *ab initio*.

B. Implied Immunity

The implied immunity argument of GlaxoSmithKline ("GSK") and Apexus is similarly flawed. At the outset, there is no dispute that vaccines are products that are expressly excluded from the federal 340B Program. GSK and Apexus's convoluted implied immunity argument rests upon the following series of transactions: (1) in 2009, Apexus submitted a bid to the Health Resources and Services Administration ("HRSA") providing an ancillary offering of vaccine sales to participants in the 340B Program, and that bid was accepted; (2) Apexus then entered into a contract with GSK that includes the sale of vaccines to participants; and (3) GSK then contracted with SNHD for the sale of vaccines. Defendants' argument fails because the implied immunity exception to antitrust liability has been narrowly construed to occur only where the following three elements are present: (a) "explicit Congressional approval of the ultimate anticompetitive effect of the challenged conduct," (b) "explicit authorization by Congress to an agency or private entity to order the challenged anticompetitive conduct," and (c) there is "no inconsistency between the challenged conduct and an express policy of the governing agency." *Phonetele, Inc., v. Am. Tel. & Tel. Co.*, 664 F.2d 716, 731-32 (9th Cir. 1981).

GSK can point to no explicit Congressional authorization to have below-market pricing for

vaccines that are not part of the 340B Program. Further, Apexus's primary witness concedes that the "value added product" contractual provisions are ancillary to 340B – thus, any connection to Congressional intent is too attenuated to fall within the implied immunity doctrine. Finally, and no less significant, GSK's contract appears to be entirely unrelated to any 340B Program because – in violation of its contract with Apexus – GSK's below-market pricing of vaccines to SNHD is explicitly contingent upon the following anticompetitive conditions:

- SNHD purchasing the vaccines exclusively from GSK, and
- SNHD purchasing a minimum quantity of the vaccines. **Ex**. **A**.[1]

Strikingly, if SNHD failed to comply with these conditions, GSK would charge SNHD the "then-applicable City/County & State contract price" for the vaccines. *Id*.[2] This provision is contrary to the 340B Program, GSK's contract with Apexus, and the entire intent behind the 340B Program.

The implied use immunity argument is completely without merit.

C. <u>Instrumentality of the Federal Government</u>

Apexus additionally argues that it is entitled to immunity because it is an "instrumentality" of the federal government. This argument fails because Apexus insisted on the inclusion of the anticompetitive conduct in an agreement with the federal government, thereby disqualifying it from immunity as an "instrumentality." *Otter Tail Power Co. v. United States*, 410 U.S. 366, 379 (1973). Moreover, immunity under the "instrumentality" concept is available to a private party only when (a) the government is acting pursuant to a clearly defined policy or program, and (b) the private party is acting at the direction or consent of the government agency. *Byers v. Intuit, Inc.*, 600 F.3d 286, 295 (3d Cir. 2010). Here, Apexus can satisfy neither element. Congress elected to create a 340B drug program ***expressly excluding vaccines*** from its coverage. There is no clearly defined policy or program to include vaccines under the 340B Program. Simply stated, Apexus is not required to "pursue a particular course of action to comply with an identifiable and specific mandate of the

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[1] All exhibits are attached to the Declaration of Richard Kellner ("Kellner Decl.") filed concurrently herewith.

[2] The 340B contracts between GSK and Apexus explicitly provides that there will **<u>not</u>** be an exclusivity or volume requirement. **Ex**. **B** [Submitted Under Seal]

regulatory statute." *Phonetele*, 664 F.2d at 733; *accord Name.Space, Inc. v. Network Solutions, Inc.*, 203 F.3d 573 (2d Cir. 2000).[3] To the contrary, Apexus was the one who sought the additional stream of income through the sale of vaccines.

In sum, Defendants' motions for summary judgment are completely without merit and should be denied in all respects.

II. STATEMENT OF FACTS

This antitrust action arises out of Defendants' abuse of a federal drug program known as the "340B Program" that Congress created to serve as a safety-net for the poor and indigent. Dkt. 154 [Amended Complaint ("FAC")], ¶ 3. To the extent GSK had actually sold vaccines under the 340B Program, it would arguably be entitled to the *Abbott* exemption from Robinson-Patman prosecution. However, Defendants recognize that vaccines are not part of the 340B Program.

GSK sold (and continues to sell) vaccines to SNHD at sharply reduced prices not available to Plaintiff and other competitors in the adult non-Medicaid market. Baktari Decl., ¶ 9-10. SNHD re-sells those vaccines to (among others) wealthy travelers who need vaccines for safaris and other overseas trips, to hotels and casinos who want to immunize their employees, and other people who are neither poor nor indigent. Baktari Decl., ¶ 11. As a result of Defendants' actions, SNHD has been able to crush private-sector competition, drive private medical clinics and doctors out of business, and move toward monopolizing the market for fee-based immunization services. Baktari Decl., ¶ 12.

A. The 340B Drug Program

In 1992, Congress created the "340B Program" when it passed the Public Health Services Act of 1992 (42 U.S.C. § 256b). At the time, Congress was "[c]oncerned" about the high drug prices charged by drug manufacturers on certain health care facilities that serve as a safety-net for the treatment of "low-income persons." *Univ. Med. Ctr. of S. Nev. v. Shalala*, 5 F.Supp.2d 4, 6 (D.D.C. 1998). In order to address this problem, Congress imposed a statutory ceiling on the prices that drug

[3] Indeed, the Apexus agreement with HRSA expressly provides that Apexus "shall operate as an independent entity and **not as an agent of the Federal Government**" and that "**[n]othing in this Agreement is intended to create an employment or agency relationship**." **Ex. D**, at pps. 1, 7 (emphasis added). For good measure, the HRSA agreement expressly requires Apexus to comply with federal law. *Id*. at 9.

manufacturers[4] can charge certain qualified health care facilities for "covered outpatient drugs." 42 U.S.C. § 256b(a)(1).

While the 340B Program requires manufacturers to provide discounts on "covered outpatient drugs" to certain qualified health care facilities, the program explicitly does **not** cover vaccines. The statute creating this program adopts the definition for "covered outpatient drugs" in section 1927(k) of the Social Security Act. *See* 42 U.S.C. § 256b(b)(1). That definition expressly excludes vaccines. *See* 42 U.S.C. § 1396r-8(k)(2)(B) (defining "covered outpatient drugs" as a "biological product, other than a vaccine . . . ."). Thus, Congress expressly carved out vaccines from the 340B Program. Indeed, SNHD admits that "vaccines are not 340B products and the 340B Drug Pricing component of the Program actually excludes vaccines." **Ex. E,** at 6:23-24; **Ex. F,** at 6:11-15.[5]

Unfortunately, despite its laudable goals, the 340B Program has been abused by individuals and entities who seek to obtain a competitive advantage against the competition. Health care facilities that obtain "covered outpatient drugs" under the 340B Program at a discount are prohibited from diverting those drugs to persons who are not patients of the facilities. Baktari Decl., ¶ 15. These facilities are expressly prohibited from "resell[ing] or otherwise transfer[ing]" a drug obtained at a discounted price under the 340B Program "to a person who is not a patient of the entity."[6] 42 U.S.C. § 256b(a)(5)(B). This resale or transfer of drugs to non-patients is referred to as "diversion," and the victims of diversion are not limited to private vaccine provider competitors of SNHD such as Plaintiff.

In a September 2011 public report, the Government Accountability Office ("GAO") warned that federal oversight of the 340B Program was "inadequate" and found that the risk of improper diversion of 340B drugs has increased significantly. *See* **Ex. G** [GAO Report to Congressional

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[4] Drug manufacturers are required to participate in the 340B Program in order to participate in state Medicaid programs. *See Astra USA, Inc. v. Santa Clara County, California*, 131 S.Ct. 1342, 1345 (2011).

[5] Congress has created separate programs that provide vaccination services. In 1993, Congress created the Vaccines for Children program, which provides free vaccines to children from birth through 18 years of age who meet certain criteria. 42 U.S.C. § 1396s. That valuable and worthy program is not at issue in this lawsuit.

[6] The HRSA has published patient definition guidelines that provide that a person is a "patient" of a covered entity only if three requirements are met. 61 Fed. Reg. 207 (October 24, 1996), p. 55157; *see also* FAC, ¶ 30. This includes that "the covered entity has established a relationship with the individual" and the "responsibility for the care remains with the covered entity."

Committees at pgs. 21, 28]. It reported that "participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance." *Id.* at p. 33. It further reported that "drug manufacturers[] have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program." *Id*. at p. 3. And it wrote that "covered entities may be inappropriately claiming 340B discounts from drug manufacturers or qualifying for the program when they should not be, potentially *increasing the likelihood that manufacturers will offset providing lower prices to covered entities with higher prices for others in the health care system*." *Id*. at pp. 26-27 (emphasis added). Thus, the federal government has expressed concern that participating entities in the 340B Program (like SNHD) are improperly using 340B discounts on drugs as a revenue-generating measure, rather than providing low-cost treatment to the poor and indigent.

In the wake of this report by the GAO, Congress conducted its own investigation into abuse and diversion of the 340B Program. In a March 2012 letter sent to Apexus, several members of Congress wrote that "[t]he *original intent* of the [340B] program was *to extend the Medicaid drug discount to the most vulnerable patients* receiving services at Public Health Service clinics, including individuals who are, medically uninsured, on marginal incomes, and have no other source to turn to for preventive and primary care services." *See* **Ex. H** [Letter from Congress at p. 1] (internal citations omitted) (emphasis added); *see also* FAC, ¶ 27. In this letter, they demanded information from Apexus about its activities and specifically demanded that Apexus "explain what 'other value-added products and services' are provided by your organization" above and beyond "negotiating drug prices and establishing distribution solutions." *Id*., at p. 2. Thus, Congress has specifically demanded information from Apexus about potential abuse of the 340B Program, including the provision of "value-added products."

B. Apexus and GSK's Abuse of the 340B Program

The 340B Program is administered by HRSA, a unit of the U.S. Department of Health & Human Services ("HHS"). Congress authorized the Secretary of HHS to "establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs." 42 U.S.C. § 256(b)(a)(8). Most recently, in 2009, Apexus was awarded a

contract by the Secretary of HHS to serve as the prime vendor for the 340B Program. *See* **Ex. I,** at p. 20; FAC, ¶ 11.

Although all Defendants acknowledge that vaccines are not included in the 340B Program, Apexus has used its power as the prime vendor for that program to negotiate discounts on vaccines on the ostensible ground that they are "value-added products" in conjunction with the Program. In a September 16, 2011 presentation about the 340B Program, a representative of Apexus explained that "we have approached all of the vaccine manufacturers, GlaxoSmithKline, Sanofi Pasteur, Merck, and Novartis, and asked for discounts that we can pass along [to participants in the Prime Vendor Program]." **Ex. I**. As a result of those negotiations, Apexus states that it has been able to successfully negotiate discounts on 25 vaccines for participating entities in the 340B Program. *See* **Ex. F,** at 6:1-3 (stating that "Apexus listed twenty-five vaccines for which it could negotiate lower prices for entities involved in the 340B Program" in its RFP response to the HRSA).

GSK has agreed to provide various vaccines to participating entities in the 340B Program at discounted prices substantially below the prices offered to private industry. None of the Defendants dispute this allegation. To the contrary, Apexus identifies multiple vaccines that GSK makes available to participating entities in the 340B Program at discounted prices that are not available to Plaintiff and other private clinics and doctors. *See* **Ex. J** at 50 [Apexus HRSA 340B Prime Vendor RFP Response) at p. 193]. Accordingly, it is undisputed that GSK engages in systematic price discrimination with respect to the sale of vaccines, even though vaccines are not covered drugs under the 340B Program.

C. SNHD's Anticompetitive Conduct and Plaintiff's Injuries[7]

Even though Congress expressly excluded vaccines from the 340B Program, and even though SNHD is not a participant in any protected 340B activity, SNHD has consistently been able to purchase vaccines from GSK at substantial price discounts not available to other health care providers based on prices negotiated by Apexus.

Although its mission as a federally qualified safety-net provider is to provide services to the poor and indigent, SNHD abuses its status as a safety-net provider to obtain an unfair and unlawful

[7] The motions for summary judgment are limited to the implied and other immunity arguments. However, these facts are provided to the Court as background for the case.

price advantage over private clinics and doctors such as Plaintiff that provide vaccination services to the adult non-Medicaid population. Baktari Decl., ¶ 16-17. SNHD purchases vaccines from GSK at discounted prices negotiated by Apexus under the 340B Program, and then resells those vaccines to the wealthy, private employers, and the general population without regard to whether those people are entitled to receive discounts under a federal program designed to serve as a safety-net for the poor. Baktari Decl., ¶¶ 18-20. In fact, SNHD has entered into lucrative contracts with casinos, hotels, and other wealthy employers (such as MGM Resorts Health Plan and Silver Nugget Gaming, LLC) that hardly fit within SNHD's mission statement or the purpose of the 340B Program. **Ex. K.** This is exactly the conduct the Supreme Court declared unlawful in *Abbott*.

Instead of focusing governmental resources on providing much needed services to children, the poor, and indigent, SNHD operates a full-fledged commercial business that generates millions of dollars in revenue annually by competing against private clinics and doctors in markets for fee-based immunization services to the adult non-Medicaid population. In particular, SNHD competes with Plaintiff in four areas: (1) travel vaccines offered to walk-in patients who require vaccinations for overseas travel; (2) occupational vaccinations offered to private businesses and government entities; (3) student vaccinations offered to allied health students and other higher education students; and (4) other fee-based general adult health vaccinations offered to the adult non-Medicaid population. Baktari Decl., ¶¶ 7, 18. As a result of its unfair price advantage, SNHD over time has succeeded in securing a high percentage of the total industry sales within these product markets in Southern Nevada. Baktari Decl., ¶ 13. Further, it has driven several private clinics and doctors who previously offered vaccination services in these markets out of business because they could not compete against SNHD's price advantage. *Id.*, ¶ 14.

Over a period of many years, Plaintiff, a private clinic that offers vaccination services to the general public for work, school, travel and general health, has suffered a substantial loss of business and revenue as a result of Defendants' wrongful conduct. Baktari Decl., ¶ 25. For illustrative purposes, the following chart provides examples of the different prices charged to SNHD and Plaintiff for contemporaneous purchases of Hepatitis A and Twinrix vaccines from GSK.

	Vaccines Obtained by SNHD from GSK			Vaccines Obtained by The Vaccine Center from GSK		
Vaccine	**Estimated Purchase Date**	**Reported Purchase Price Per Dose**	**Reported Resale Price**	**Purchase Date**	**Purchase Price Per Dose**	**Resale Price**
Hepatitis A	April 2012	$22.02	$40.00 to $50.00	April 2012	$62.34	$84.00
Twinrix	April 2012	$50.26	$70.00	April 2012	$90.09	$139.00

Baktari Decl., ¶ 26. As this chart demonstrates, Plaintiff purchases the exact same vaccines from GSK at prices almost twice or three times as high as the purchase price offered to SNHD. *See id.* Further, Plaintiff's purchase price is significantly higher than SNHD's resale price to the general public—which seriously cripples Plaintiff's ability to compete against SNHD for any non-Medicaid customers.

As a result of GSK's discriminatory pricing negotiated by Apexus as the prime vendor of the 340B Program, Plaintiff has alleged that SNHD has obtained or is attempting to obtain monopoly power in the markets in which it competes with Plaintiff and other private clinics and doctors. As a consequence, competition in the relevant markets has been substantially lessened as SNHD has driven private competitors who cannot obtain similar discounts out of business. FAC, ¶¶ 4, 46, 47, 53. This loss of private competition ultimately harms consumers who find that vaccination services from high-quality private businesses are no longer available, thereby reducing the number of options for consumers. *See id.* Likewise, it injures taxpayers who must foot the bill for the expenditure of governmental resources on vaccination services to the wealthy and other people who don't need to use a safety-net for health care services. *See id.*, ¶ 5.

Through this action, Plaintiff seeks to hold Defendants accountable for abuse and diversion within the 340B Program and to enjoin their unlawful activities. It brings causes of action against Defendants for price discrimination under the Robinson-Patman Act and various state law claims. *Id.*, ¶ 6.

III. LEGAL STANDARD FOR SUMMARY JUDGMENT

Summary judgment is appropriately awarded only when, viewing the evidence in the light most favorable to the non-moving party, "there are no genuine issues as to any material fact . . . and the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). The summary judgment standard was recently set forth by this Court in *Branch Banking & Trust Co. v. Desert Canyon Phase II LLC*, 2014 WL 2468610, *1-2 (D. Nev. June 2, 2014), and incorporated in full herein.

IV. ARGUMENT

It is well-established by Supreme Court authority that state and local governmental entities engaged in commercial activities are not immune from federal antitrust laws and cannot use their superior purchasing power to suppress private competition in violation of the Robinson-Patman Act. *See Jefferson County Pharm. Ass'n, Inc. v. Abbott Labs.*, 460 U.S. 150, 170 (1983). Defendants do not question the validity of *Jefferson County*, but claim they are immune from prosecution for predatory anticompetitive practices because: (1) SNHD's sale of vaccines is exempted under the Robinson-Patman Act by the NPIA, in that the vaccines are for its "own use"; (2) GSK and Apexus are entitled to "conduct-based" government immunity because HRSA included vaccines within the 340B Program as "value added" products; and (3) Apexus is entitled to immunity because it is an "instrumentality" of the federal government.

SNHD's sale of vaccines to "walk-in" customers (as well as casinos and other businesses that they actively solicit) falls outside of the "own use" doctrine. As the Supreme Court ruled in *Abbott*, "own use" immunity does not apply to pharmacy prescriptions for walk-in customers "that have no present connection with the hospital and its pharmacy other than to have its prescription filled." *Abbott*, 425 U.S. at 17-18.

The implied immunity argument similarly fails. There is no explicit Congressional authorization for below-market priced sales of vaccines that are not part of the 340B Program. The "value added product" contractual provisions are completely ancillary to the 340B contracts – thus, any connection to Congressional intent is too attenuated to fall within the implied immunity doctrine. Finally, and no less significant, GSK's contract appears to be entirely unrelated to any 340B program

because – in violation of its contract with Apexus – the below-market pricing is contingent upon (a) GSK being the exclusive supplier of vaccines to SNHD, and (b) SNHD meeting certain volume purchase requirements.

Apexus's independent argument that it is immune as an instrumentality of HRSA also fails because, among other reasons, it initiated and suggested that vaccines become part of the 340B Prime Vendor Program. Again, conduct-based immunity does not arise from something that was initiated by a defendant. Here, it was Apexus who initiated, submitted, and requested that vaccines be part of the "value added" program. Accordingly, Apexus cannot make the instrumentality immunity argument.

For all of these reasons, Defendants' motion for summary judgment on immunity grounds should be denied in all respects.

A. SNHD's Commercial Solicitation and Sale of Travel Vaccines to Businesses and "Walk-In" Customers Who Were Not Previously SNHD Patients Is Not Covered by the "Own Use" Immunity

SNHD (at pp. 10-12) contends that its sale of travel vaccines to businesses and individuals is immune from Robinson-Patman liability under the NPIA because the vaccines are for its "own use."[8] In making this argument, SNHD largely ignores the Supreme Court's ruling in *Abbott*, 425 U.S. at 17-18, where it narrowly construed the "own use" doctrine to existing patients of the alleged covered entity. There is no proof, whatsoever, that SNHD has a prior relationship with the individuals to whom it provides travel vaccines. Indeed, through discovery, Plaintiff has uncovered contracts that SNHD enters with Las Vegas businesses to provide immunization services for their employees.

Immediately before Plaintiff commenced this action, SNHD openly operated what it called the "Workplace Vaccination Program" – a program specifically designed to solicit businesses to provide vaccination services to their employees. *See, e.g.*, **Exs. K, L**. Far from focusing upon the impoverished and vulnerable members of the Nevada community, SNHD solicited businesses such as MGM Resorts to provide workplace vaccinations. **Ex. K**. Significantly, the form solicitation letters explicitly recognized that the employees were not current patients of SNHD. Rather, the provision of services was contingent upon the individual still being an employee of the business, and the right to

[8] Apexus and GSK similarly argue that if SNHD is exempt from Robinson-Patman liability under the NPIA, then they are not liable for the sale of those vaccines under Robinson-Patman as well.

receive the immunization services would end:

> A notification letter of any employee termination must be on file with SNHD to prevent administration of vaccines to persons no longer authorized to receive vaccines at your company's expense. Your company will be responsible for payment of the above vaccines administered to individuals who have terminated employment, but the SNHD has not received notification of such termination.

Ex. K.

Indeed, until this action was commenced, SNHD described the Workplace Immunization Program as follows:

> The Southern Nevada Health District offers an opportunity for employers to offer immunizations to staff. A health workplace protects employees and ensures productivity. The health district's workplace vaccination program offers convenient vaccination services and record-keeping.

Ex. L.

However, after this lawsuit, SNHD distanced itself from the active solicitation program, and issued the following Immunization Program Policy Statement:

> Businesses will no longer need a formal agreement to have their employees receive adult vaccinations at any one of our five vaccine locations across southern Nevada. Those employees may continue to receive appropriate adult vaccines with remittance being provided at the time of service.

Ex. M.

Of course, all of the foregoing was part and parcel of the SNHD's overall operation of a business that directly competed with private health clinics. The outreach to non-patients is evident from even its current website, which solicits patients for "Travel Vaccines" – as far from the "prevention of disease" mandate that SNHD uses for its "own use" arguments:

> <u>Travel Vaccines</u>
>
> The health district offers vaccines for people traveling outside the United States. As with most immunizations, travel vaccines often require several weeks to provide complete protection. It is recommended that travel vaccines are administered as soon as possible.

Ex. N.

Indeed, the price of the vaccines is explicitly stated as being the cost at which SNHD receives the vaccines plus a $20 administrative charge for the first vaccine, and $6 per vaccine thereafter. *Id.*

Further defeating any argument that SNHD might have that it is concerned with administering to the health of Nevada citizens (and, by the way, there is no explicit restriction of the services to Nevada citizens), SNHD admits that they do not provide doctor consultations in connection with the sale of vaccines. *Id.*

At a minimum, the foregoing creates material issues of fact that defeat summary judgment based upon the "own use" exemption under the NPIA.

1. *Abbott and the "Limited" NPIA Exemption*

As far back as 1976, the Supreme Court established the contours of the interplay between the Robinson-Patman Act and the NPIA. The Robinson-Patman Act seeks to protect small businesses, like Plaintiff, from the devastating effects of massive price discounting which forecloses effective competition. The NPIA seeks to facilitate health care for low income persons who would otherwise be unable to acquire such care. The legislative balance reached was to provide a limited immunity when a specified clinic or hospital provides medical services to its low-income patients.

In *Abbott*, 425 U.S. at 29-30, the owners of pharmacy companies brought an antitrust action against certain drug manufacturers alleging that they sold pharmaceutical drugs to certain hospitals at prices below those charged to private pharmacies. The defendants claimed that the sales were exempt from the Robinson-Patman Act because they were to non-profit hospitals that purchased the drugs for their "own use." The Supreme Court analyzed seven different categories of drug sales, some of which constituted violations of the Robinson-Patman Act and others which did not.

The parties all conceded that inpatient and emergency room treatment at the hospital fell within the "own use" exemption. The Supreme Court then undertook its analysis of the remaining categories of sales, bearing in mind that Robinson-Patman Act protections are to be liberally construed, and exceptions to the application are to be strictly construed. *Abbott*, 425 U.S. at 11-12. Further, "implied antitrust immunity is not favored." *Id.* at 12. The Court rejected an expansive interpretation of the NPIA that "there is nothing in the Act that indicates that its exemption provision is to be applied and expanded automatically to whatever new venture the nonprofit hospital finds attractive in these changing days." *Id.* at 13. That is precisely what has occurred in this case.

The outer limits of the NPIA is exemplified by the categories that fall outside of the "own use"

exemption. The Court ruled that "the refill for the hospital's former patient is on the other side of the line that divides that which is in the hospital's 'own use' from that which is not." The rationale for this distinction was that "[inevitably], . . . there comes a point where the dispensation of pharmaceutical products is not for the institution's 'own use.'" *Id.* at 15. Thus, when the patient leaves the hospital, former connection that existed when the patient was in the hospital becomes too "attenuated" to be considered the hospital's "own use." *Id.* at 16.

> The easiest line for the Court to draw was with respect to "walk-in" prescription buyers.
>
> The walk-in prescription buyer for the most part affords little difficulty for us in the context of [the NPIA]. Even though one acknowledges the full weight of the argument that the modern hospital is a different institution from what it was when the [NPIA] was adopted in 1938, and that increasingly it has become a focus of health care in the community, the extension of [the NPIA] to the walk-in customer, who has no present connection with the hospital and its pharmacy other than as a place to have his prescription filled, would make the commercially advantaged hospital pharmacy just another community drug store open to all comers for prescription services and devastatingly positioned with respect to competing commercial pharmacies. This would extend the hospital's "own use" concept beyond that contemplated by Congress in [the NPIA].

Id. at 17-18.

The Supreme Court made it crystal clear that "Congress surely did not intend to give the hospital a blank check" to extend this limited purpose discount indiscriminately:

> We therefore conclude that the exemption provision of the Nonprofit Institutions Act **is a limited one**; that just because it is a nonprofit hospital that is purchasing the pharmaceutical products does mean that all its purchases are exempt from Robinson-Patman; that the test is the obvious one inherent in the language of the statute, namely, "purchases of their supplies for their own use"; and that "their own use" is what reasonably may be regarded as use by the hospital in the sense that such use is part of and promotes the hospital's intended institutional operation in the care of **persons who are its patients**.

425 U.S. at 30 (emphasis added).

Here, beyond just dealing with only "walk in" customers, SNHD actively solicits businesses and the public to use their services in active competition with private doctors who sell vaccine and vaccine-related services. Thus, the NPIA "own use" exemption does not lie.

a. Defendants' Attempt to Circumvent the Plain Ruling in *Abbott* Fails

On its face, SNHD's "own use" argument fails because its arguments go far, far beyond just

"walk-in" customers. Under its Workplace Immunization Program, SNHD actively solicits non-patients to use its services – acting in direct competition with competitively disadvantaged private clinics offering the same services. Further, it also actively solicits the "walk-in" patients for its travel vaccine services. Indeed, by its nature, the travel vaccine services are hardly something that require immediate treatment of an existing "patient."

Notwithstanding the direct rejection of the "everyone is our patient" argument in *Abbott*, SNHD claims (at 10:2-18) that everyone in Nevada is within its patient base because the function of SNHD is to "promote, protect, and preserve 'the health, the environment and well-being of Southern Nevada residents and visitors." This argument fails, *ab initio*, because *Abbott* is good law and there is no case precedent that Defendants can cite to that allows for such an "exception" to Robinson-Patman that would effectively swallow the rule.[9]

b. *De Modena* and the FTC Advisory Opinions Are Inapposite

The Ninth Circuit's decision in *De Modena v. Kaiser Foundation Health Plan, Inc.*, 743 F.2d 1388 (1984) does not save SNHD from liability under the Robinson-Patman Act. In *De Modena*, the Ninth Circuit ruled that "any sale of drugs by an HMO to one of its members falls within the basic function of the HMO" because an HMO is organized to provide "continuing and often preventive health care for their members." *Id.* at 1393. On the other hand, it reaffirmed that sales "to walk-in customers who are not members of a Kaiser-Permanente HP" are not for the health care provider's "own use" and therefore fall outside the NPIA's safe harbor. *Id*. at 1394. Thus, the controlling distinction in *De Modena* was whether the person being treated could be reasonably considered a patient of the HMO with a present connection to the HMO above and beyond that person's interest in purchasing the pharmaceuticals – a standard entirely consistent with the test established by *Abbott*.

[9] The mere fact that SNHD's mission statement provides that its mission is to "protect and promote the public health" does not magically create a contractual or patient-doctor relationship between SNHD and everyone within the geographic boundaries that SNHD serves. Likewise, the Nevada law that authorizes the State Board of Health to pass "reasonable regulations consistent with law" to "define and control dangerous communicable diseases" and to "protect and promote the public health generally" says nothing whatsoever about creating a patient-doctor relationship. *See* N.R.S. 439.200. Nor does it preempt the Robinson-Patman Act. To the contrary, SNHD must still comply with the Robinson-Patman Act, and it may not use its non-profit status to unfairly compete against and annihilate private competition. *See Jefferson County*, 460 U.S. at 171.

Here, SNHD can hardly claim that all the residents and visitors of Southern Nevada are its patients with an actual present connection to the Health Department. Unlike the HMO at issue in *De Modena* which contracted "with customers who wish[ed] to become members and provide[d] them with medical care in return for monthly dues" (*id*. at 1390), SNHD certainly has not entered into contracts with everyone who lives in or visits Southern Nevada to provide health care services. Nor does SNHD have a "prior" or "continuing relationship" with an open population consisting of all Southern Nevada residents and visitors. *See In re Brand Name Prescription Drugs Antitrust Litig.*, 1994 WL 715848, *3 (N.D. Ill. Dec. 4. 1995) (explaining that "HMOs provide comprehensive health care services, including continuing and preventive care, to a closed population of members to whom it has an ongoing obligation based in contract"). There is absolutely no proof that SNHD provided any other healthcare services to the adult non-Medicaid individuals receiving these drastically discounted vaccines, further demonstrating the lack of the "prior" or "continuing relationship" required for SNHD to claim the "own use" exemption.

GSK's citation (at p. 16) to a CarePartners FTC opinion letter is utterly self-defeating. The advisory opinion is entirely consistent with Plaintiff's interpretation of *Abbott* and applicable law. The FTC made the limitations of its holding clear, on page 5 of the opinion letter: "We emphasize, however, that the NPIA exemption is dependent on the maintenance of an ongoing relationship between CarePartners and the patients." Dkt. 168-9 at 6. Here, this case, as in *Abbott*, involves in the inapposite situation of walk-in patients with no ongoing relationship with SNHD.[10] The full import of the CarePartners opinion letter is that the ongoing patient relationship can exist outside of the hospital. However, the predicate that must be established is of an "ongoing" patient relationship. That simply does not exist here.

SNHD's citation to the FTC opinion letter for Stevens Hospital [Dkt. 161-4] and Quest [Dkt. 161-5] is also self-defeating. Stevens Hospital relates to the filling of pharmacy prescriptions by the hospital for patients receiving treatment from its clinic physicians. The FTC emphasized the ***ongoing***

[10] The FTC described this relationship as follows: "The in-home hospice patients are treated by CarePartners staff physicians, and these physicians maintain an ongoing relationship with the in-home patients until the time of death." Dkt. 156-9 at 6.

patient relationship, and ruled:

> Based on the factors discussed above, it is our opinion that the clinic pharmacies may dispense products purchased under the NPIA to all patients who are treated at clinics staffed by employed physicians **and who are under the continuing care of such physicians. Walk-in customers to Stevens' retail pharmacy, Hadfields, on the other hand, would not be eligible to receive reduced price pharmaceuticals, as those patients would not be considered to be under the ongoing care of a Stevens' physician.**

Dkt. 161-4, p. 3 (emphasis added).

In fact, the FTC opined that a customer is not considered a patient if he or she is treated by another doctor, and the prescription would not be deemed "own use." The key is whether the patient is subject to ongoing care. *Id.* The Quest opinion letter is even more far removed, because it only involves the institution's employees, retirees, and their dependents. Dkt. 161-5, p. 2. It does not cover "walk-in" or non-patients whose purchase of vaccines are solicited. *See also* Kaiser letter [Dkt. 161-3] (application of "own use" to existing Kaiser plan members).

In *Abbott*, the Court looked into each category of pharmaceutical sales to determine whether they are covered by the NPIA. In contrast, Defendants' summary judgment motions claims a blanket exemption under the NPIA. As demonstrated herein, walk-in patients – let alone those who are actively solicited by SNHD through the internet and Workplace Immunization Program – do not provide any Defendant with any Robinson-Patman exemption under the NPIA. Defendants' motion for summary judgment should be denied.

B. GSK and Apexus Have Not Proven as a Matter of Law that They Are Immune to Antitrust Liability on a Conduct-Based Immunity Theory

GSK and Apexus argue that they are immune to antitrust liability based on a conduct-based federal instrumentality theory. This argument fails based upon the true nature of the 340B Program, and the process by which vaccines were included in Apexus's contract with HRSA.

Under the federal instrumentality doctrine, "immunity is provided to a private party acting anti-competitively pursuant to an agreement with a government agency [only] when: (1) the government agency is acting pursuant to a clearly defined policy or program; and (2) the private party is acting at the direction or consent of the government agency." *Byers*, 600 F.3d at 295; *PGMedia, Inc. v. Network*

Solutions, Inc., 51 F.Supp.2d 389, 401 (S.D.N.Y. 1999). And even if this two-part test is otherwise satisfied, the private party is still subject to antitrust liability if it had insisted on the inclusion of the anticompetitive restrictions in its agreement with the federal government. *See Otter Tail*, 410 U.S. at 379.

The overall context of this analysis is important, as the Ninth Circuit has instructed: "[c]ourts have generally framed the antitrust immunity issue in terms of whether Congress intended to repeal the antitrust laws with respect to the particular industry when it enacted the regulatory scheme." *Northrop Corp. v. McDonnell Douglas Corp.*, 705 F.2d 1030, 1056 (9th Cir. 1983). Importantly, "[t]here is no general presumption that Congress intends the antitrust laws to be displaced whenever it gives an agency regulatory authority over an industry." *Phonetele*, 664 F.2d at 729. Instead, the Ninth Circuit has repeatedly held that a statute or regulation confers implied antitrust immunity only where the following three elements are satisfied. There must be: (1) "explicit congressional approval of the ultimate anticompetitive effect of the challenged conduct;" (2) "explicit authorization by Congress to an agency or private entity to order the challenged anticompetitive conduct;" and (3) "no inconsistency between the challenged conduct and an express policy of the governing agency." *Id.* at 731-32; *see also Northrop*, 705 F.2d at 1056-57.[11]

Defendants' arguments fail because: (a) the vaccines are apparently purchased outside of the 340B Program through independent GSK contracts with SNHD; (b) the inclusion of the vaccines as part of Apexus's contract was at Apexus's behest as part of its proposal for a contract; and (c) there is no "clearly defined [agency] policy or program" that "direct[s]" it or the other defendants to engage in the alleged anti-competitive conduct. *See Byers*, 600 F.3d at 295.

[11] Plaintiff does not dispute that Defendants may be immune from antitrust liability for their involvement in selling and purchasing covered outpatient drugs – as opposed to *vaccines* – at a price discount under the 340B Program. Congress expressly imposes a statutory ceiling on the prices of "covered outpatient drugs" that may be charged to covered entities under the 340B Program. *See* 42 U.S.C. § 256b(a). Within the ***limited*** boundaries of the 340B Program, Congress has explicitly authorized price discrimination with respect to "covered outpatient drugs," and choosing to treat vaccines differently by excluding vaccines from the definition of "covered outpatient drugs." *See* 42 U.S.C. § 256b(b)(1); 42 U.S.C. § 1396r-8(k)(2)(B) (defining "covered outpatient drugs" as "a biological product, other than a vaccine . . . "). Of course, even this exemption would not help Defendants because the products can ***only be sold to patients*** (*supra* at p. 5:1-2, n.5), and not episodic walk-in or solicited customers.

1. GSK Has Entered into Contracts to Sell Vaccines Directly with SNHD, Apparently Outside of the 340B Program

At the outset, the "implied immunity" argument fails because GSK's sale of vaccines was not part of the 340B Program – or even as part of the "value added" submissions by GSK in connection with its 340B bid. To the contrary, SNHD's below-market purchases of vaccines predated the alleged 340B "value added" provisions and, in any event, are based upon completely independent contracts.

In the limited productions provided by Defendants, it appears that GSK's contract with SNHD for the sale of vaccines was first entered on October 29, 2007. This is based upon the reference to the date of the first agreement in the third amendment to that agreement, dated November 10, 2010. **Ex. A**. Unfortunately, Defendants have refused to produce the original contract. Kellner Decl., ¶ 3. The October 29, 2007 date is significant because it pre-dates SNHD's February 2008 enrollment into the 340B program (**Ex. O**) – revealing that the true contractual relationship for the sale of vaccines is independent of the 340B Program.

Indeed, GSK's contract specifically provides that its below-market pricing for Havrix (Hepatitis A) "is contingent upon continued SNHD's exclusive use of Havrix Adult Vaccines . . . for all of its requirements for Hepatitis A vaccine." **Ex. P**. The Second Amendment then states:

> If SNHD fails to satisfy the condition set forth herein, then the price for the [Havrix] identified above from the date of the non-conforming purchase shall be the then-applicable City/County& State contract price for such NDC.

Id.

Further, the contract had a minimum volume requirement of 90,000 dosages of Havrix during the contract period. *Id.* In the event the minimum volume requirements are not met, then "GSK and SNHD shall discuss whether adjustments to the pricing set forth herein are appropriate." *Id.* Interestingly, on October 15, 2010, GSK wrote a letter to SNHD waiving the "90,000 dose purchase requirement" for Havrix "in order for SNHD to receive discounts/rebates under the Contract." **Ex. Q**. GSK conditioned the waiver upon SNHD purchasing at least 75,000 doses of Havrix Adult vaccines. *Id.*

Thereafter, in an August 31, 2011 email to SNHD, GSK noted that SNHD was not meeting its volume requirements, notwithstanding the fact that GSK was providing SNHD with CDC Hepatitis A

vaccine pricing. **Ex. R**. This reference to CDC pricing is quite curious (and evidently representative of the fact that GSK was not selling vaccines as a "value added product"), since SNHD was not purchasing vaccines under a CDC program. This fact was confirmed by Plaintiff's prior counsel, retired United States Senator Richard Bryan, in a meeting he had with SNHD officials who affirmatively stated that SNHD was not part of any CDC program. Bryan Decl., ¶ 7.

The Third Amendment to the Havrix Agreement, dated November 10, 2011, contained similar language regarding exclusivity and volume requirements for pricing, as well as the fail-safe of City/County & State contract pricing if the exclusivity/volume requirements were not met. **Ex. A**. Remarkably, on April 10, 2012, SNHD affirmatively deactivated its 340B PVP contract and decided to remain on a Minnesota Multi-State contract. **Ex. S**.[12] This is not surprising since it was not receiving its below-market priced vaccines through any aspect of the 340B Program, but through its independent contract with GSK.

Thus, at a minimum, summary judgment should be denied on this issue because Defendants cannot prove as a matter of law that all of SNHD's vaccine purchases during the subject time period was through any aspect of the 340B Program.

2. Even If SNHD's Purchase from GSK Were Somehow Part of a "Value Added" Feature of the 340B Program, Implied Immunity Does Not Apply

Defendants cannot prove that purchases of vaccines through a "value added" feature of the 340B Program (if that actually occurred) is subject to implied immunity exemption. The narrow circumstances under which implied immunity can apply have been thoroughly established.

"Conduct is exempt from the antitrust laws only when the regulated entity is required to pursue a particular course of action to comply with an identifiable and specific mandate of the regulatory statute." *Phonetele*, 664 F.2d at 733; *Name.Space*, 202 F.3d at 581 (holding that the applicability of the federal instrumentality doctrine depends "on the extent to which the federal government or its agencies directly own and/or exercise plenary control over the entity in question"). Thus, implied antitrust

[12] While it is possible that SNHD reactivated its 340B PVP contract with Apexus at a later date, the mere fact that it was deactivated lends further support to the fact that SNHD's contractual relationship for the purchase of vaccines at below-market prices is independent of the 340B Program.

immunity is found only where there is a "pervasive regulatory scheme," where an antitrust exemption is "necessary to make the [statute] work, and even then only to the minimum extent necessary." *Strobl v. N.Y. Mercantile Exch.*, 768 F.2d 22, 26 (2d Cir.), *cert. denied*, 474 U.S. 1006 (1985).

The Ninth Circuit's decision in *Phonetele* is especially instructive. In that case, a government contractor argued that it was immune from antitrust liability because "the challenged activity was subject to regulation by an agency under a pervasive or comprehensive regulatory scheme" and the regulative agency had approved of the anticompetitive tariffs when it "permitted them to go into effect." *Phonetele*, 664 F.2d at 729, 733. The Ninth Circuit, in an opinion authored by Justice Kennedy, rejected these arguments. Although the Federal Communications Commission ("FCC") had allowed the challenged tariffs to go into effect, the Ninth Circuit ruled that the tariffs were "the product of the regulated entity's independent initiative and judgment." *Id*. at 735. It reasoned that the FCC was "not required under law to pass any judgment on a proposed tariff, and it does not necessarily approve as agency policy the content of every tariff permitted to go into effect." *Id*. at 730, 733. Further, there was no congressional mandate or express agency policy that compelled the defendant to adopt the tariffs in the first instance. *Id*. at 730-31. Under these circumstances, Justice Kennedy explained that there was no "actual conflict" between antitrust law and the regulatory scheme and therefore it is not unfair to subject the regulated entity to antitrust liability for its anticompetitive practices. *See id*. at 732-33.

a. There Is No Conflict between Robinson-Patman and the 340B Program

Here, there is no "actual conflict" between the applicable regulatory scheme and the imposition of antitrust liability on Defendants in this case. Unlike covered outpatient drugs for which a statutory price ceiling exists to benefit covered entities participating in the 340B Program, Defendants fail to identify any applicable statute or regulation that directs or compels drug manufacturers to sell vaccines at discriminatory prices in a manner that is inconsistent with the Robinson-Patman Act. Had Congress wanted vaccines to be included in the 340B Program, it could easily have added such a provision to the governing statutes. But it did not do that.

Indeed, in congressional testimony on December 15, 2005, the then Deputy Administrator of the HRSA explained:

> The purpose of the [340B] program is to limit the costs of covered outpatient drugs to federally funded grantees and other safety-net health care providers referred to as covered entities. By expanding access to affordable drugs, the 340B program plays an important role in eliminating health disparities and improving the health of the uninsured and underinsured.

Ex. T, at p. 14. Further, the HRSA advises against the "[d]iversion" of drugs obtained through the 340B Program "to individuals who are not patients" (**Ex. U,** at p. 14), and HRSA acknowledges that "vaccines are not covered under the 340B Program" (**Ex. V,** at p. 55). Nevertheless, GSK indiscriminately provides discounts on vaccines to covered entities in the 340B Program without regard to its anticompetitive effects in retail vaccine markets for the adult non-Medicaid population.

In congressional testimony on December 15, 2005, the then Senior Director of the 340B Prime Vendor Program testified that the 340B Program's "contract portfolio also includes discounts for important products such as vaccines, diabetic meters, and test strips which are ***not required*** to be discounted through the 340B program . . . ." **Ex. T,** at p. 64 (emphasis added).

Apexus (at pp. 12-15) contends that HRSA is entitled to "deference" to fill in the gap (i.e., vaccines) when implementing the statute or regulation. As previously shown, the statute creating the 340B program adopts the definition for "covered outpatient drugs" in section 1927(k) of the Social Security Act. *See* 42 U.S.C. § 256b(b)(1). That definition expressly excludes vaccines. *See* 42 U.S.C. § 1396r-8(k)(2)(B) (defining "covered outpatient drugs" as a "biological product, other than a vaccine . . . ."). Thus, Congress expressly carved out vaccines from the 340B Program. There is no "gap" that required any interpretative role by HRSA for which deference could possibly attach. *United States v. Mead Corp.*, 533 U.S. 218, 227-28 (2001). For this reason alone, administrative deference fails.

Further, the availability of administrative deference hinges on the degree to which there is proof of a thorough evaluation, the formality of the decision and the degree of the agency's care, or express Congressional authority for there to be expansive rulemaking. *Id.* at 228. As the Court ruled in *Christensen v. Harris County*, 529 U.S. 576, 596-97 (2000), when there is doubt that Congress actually intended to delegate particular interpretative authority to an agency, *Chevron* deference is inappropriate. This is especially so when there was no "notice and comment" process. *Mead*, 533 U.S. at 231-33. Here, Defendants have failed to presents facts that are even remotely close to those in which administrative deference has been applied. There is no basis for administrative deference.

Vaccines were not part of the 340B Program. In reality, the contractual "value added" was a bone sent out at the request of covered entities.[13] This argument is another "red herring."

b. In Any Event, Implied Antitrust Immunity Is Inapplicable Here Because the Inclusion of Vaccines in the Apexus Contracts Was Voluntary and at the Behest of Apexus and Covered Agencies

Apexus explicitly admits that the inclusion of vaccines came at the behest of "covered entities" – *i.e.*, institutions like SNHD (Mitchell Decl., ¶ 12) and the manufacturers must "voluntarily offer their products." *Id.*, ¶ 13. Thus, as a matter of law, implied immunity cannot apply because the inclusion of below-market vaccines came at the request of the "covered entities."

Conceptually, this distinction is significant because implied immunity requires direct government action and involvement. When a government contractor tries to expand its offerings (so that it can get a greater volume of business and commissions), this is not something that can conceivably be covered by implied immunity. If that were so, then Apexus could sell every possible medical product below market and drive every private doctor out of business. This is a ridiculous position, that has absolutely no support in case law or fact.

Finally, GSK's imposition of volume and exclusivity requirements in its contract with SNHD for below market pricing takes it – and all of the defendants – completely outside of any possible implied immunity argument. **Ex**. **A**. Strikingly, GSK's agreement with Apexus provides that GSK cannot impose any "purchasing commitment on a Participant . . . as a condition to the Participant's . . . purchase of any Products pursuant to this Agreement." **Ex**. **B**. When GSK actually imposes such requirements in its contracts with SNHD, it necessarily loses any possible argument of implied or instrumentality immunity.

Accordingly, Defendants simply have not upheld their burden of proving that the anticompetitive practices at issue were done at the direction of the federal government. *See Phonetele*, 664 F.2d at 729, 733 (reasoning that the mere fact that the FCC allowed tariffs to go into effect did not

[13] Indeed, when looking at Mr. Mitchell's declaration, his manufactured reason for allowing vaccines – to prevent the spread of disease – is completely irrelevant in connection with the travel vaccines that are the subject of this antitrust action. Baktari Decl., ¶ 35. Further, the unabashed sale beyond "own use" to casino employees and walk-in customers does nothing to further this manufactured ex post facto rationalized purpose.

mean that those tariffs could not be challenged as a violation of antitrust law).[14] Indeed, Congressional investigations were undertaken to determine if there was diversion by selling drugs to those who are not *vulnerable patients* who have no other source to turn to for preventive and primary care services. *See supra*, pp. 5-6. It was not to be used as a means for expanding sales for drug manufacturers and entrepreneurial government agencies.

In the absence of a convincing showing of "clear repugnancy" between the antitrust laws and the regulatory system that governs sales of vaccines for use with the adult non-Medicaid population, it is crucial that the antitrust laws in this case be enforced. *See Phonetele*, 664 F.2d at 732-33.

3. Unlike Apexus, GSK Cannot Claim That It Is in Privity with Any Federal Agency

Unlike Apexus, GSK cannot argue that it has any privity with any federal agency.[15] While Apexus has at least been able to cite a government contract that it entered into with the HRSA as the alleged source of its antitrust immunity, GSK does not and cannot identify any contract that it has entered into with any federal agency. For this reason alone, all the conduct-based immunity cases relied on by GSK are easily distinguishable and ultimately unavailing to GSK.

The two primary cases that GSK relies upon are the decisions of the Second and Third Circuits in *Name.Space* and *Byers*. In both cases, the courts ruled that government contractors were immune from antitrust liability because agreements with federal agencies required them to engage in the alleged anticompetitive conduct.[16]

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[14] *See also United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 225-28 (1940) (approval or knowledge of the federal authorities about a private entity's conduct does not create immunity for that conduct); *Union Carbide & Carbon Corp. v. Nisley*, 300 F.2d 561, 577 (10th Cir. 1961) (defendant was not immune from antitrust liability where, in carrying out the government's program, it fixed prices with another defendant in furtherance of their plan to monopolize the vanadium industry, even though the government officials knew of and indirectly approved the program which violated the antitrust laws).

[15] Like GSK, SNHD is not in privity with the federal government. Accordingly, it does not even bother to make a conduct-based immunity argument.

[16] GSK also cites several other cases as support for its conduct-based immunity argument. Like *Name.Space* and *Byers*, however, all of those cases are distinguishable because they involved government contractors who were required by the terms of a contract with the federal government to engage in the anticompetitive conduct at issue. *See IT&E Overseas, Inc. v. RCA Global Communications, Inc.*, 747 F.Supp. 6, 11-13 (D.D.C. 1990).

In *Name.Space*, the plaintiff alleged that the defendant violated antitrust laws when it refused plaintiff's request to add new top level domain names to the "Domain Name System" managed by defendant under its contract with the National Science Foundation ("NSF"). *Name.Space*, 202 F.2d at 576. The government contract, however, required the defendant "to obtain prior written approval from the NSF Grants Officer whenever there are significant changes in the project or its direction." *Id*. at 583. When defendant asked the NSF to grant plaintiff's request, the NSF refused to give the written approval contemplated under the agreement. *Id*. The Second Circuit thus held that the defendant's alleged misconduct was compelled by the explicit terms of the government contract with the NSF. *Id*. at 582. Further, an NSF "White Paper" articulating the agency's policy objectives "expressly state[d]" that "the stability and future development of the [Domain Name System] is best served by not adding any new [Top Level Domain names] during" a transition period. *Id*. Accordingly, in light of the evidence presented at summary judgment, the Second Circuit affirmed the district court's grant of summary judgment on implied immunity grounds. *See id*. at 580-83.

Byers is also distinguishable. In that case, a class action was filed on behalf of U.S. taxpayers against the I.R.S. and a government contractor alleging that their agreement to charge taxpayers fees to electronically file their tax returns was unlawful. *Byers*, 600 F.3d at 289-90. The agreement imposed an upper limit on the percentage of taxpayers who could be offered free electronic filing services in order to create an incentive for businesses to enter the market and to ensure that e-filing vendors would not go out of business. *Id*. The district court dismissed the Sherman Act claim on the ground that the contractor was "entitled to conduct-based implied antitrust immunity and therefore shielded from antitrust liability, since their anticompetitive behavior was required by the IRS pursuant to the 2005 agreement." *Id*. at 291. The Third Circuit affirmed the decision and explained that 1) the I.R.S. was statutorily authorized to enter into the agreements, and 2) the provisions in the agreement expressly directed the contractor to restrict the availability of free electronic filing services under the program. *Id*. at 295.

Unlike the defendants in *Name.Space* and *Byers*, GSK is not a government contractor and therefore cannot assert that a government contract required it to engage in the anticompetitive actions at issue in this action. At its very best, the contract between Apexus and the HRSA arguably requires

Apexus (not GSK) to negotiate price discounts on covered outpatient drugs with drug manufacturers—it certainly does not require GSK to actually provide discriminatory price discounts on vaccines, especially when those discounts have anticompetitive effects. After all, GSK is not even a party to the contract.

In short, GSK is not relieved of its legal obligations to comply with the Robinson-Patman Act and must do so in its negotiations with Apexus over the price of vaccines. In any event, the diversion of low-cost vaccines obtained through a safety-net health care program to casinos and hotels on the Las Vegas strip and wealthy travelers planning an exotic trip overseas frustrates the policy objectives of the 340B Program.

4. SNHD Cannot Claim Implied Antitrust Immunity

SNHD has absolutely no basis for claiming implied antitrust immunity. SNHD does not and cannot cite any federal law or policy that directs or compels SNHD to purchase vaccines at a discount under the 340B Program. To the contrary, SNHD admits that "vaccines are not 340B products and the 340B Drug Pricing Component of the Program actually excludes vaccines." **Ex. E,** at 6:23-24; *see also* Dkt. 161 [SNHD MSJ] at 3:14.

Moreover, SNHD's anticompetitive actions are inconsistent with the letter and spirit of the 340B Program, which was designed to provide low cost covered outpatient drugs to health care providers that serve as a safety-net for the poor and the indigent. That program was never intended to provide local or state governmental entities with a weapon to unfairly undercut private competition in the retail markets for fee-based immunization services to wealthy travelers, hotels, casinos, or other people who are not in need of safety-net services. As a result of its unlawful competitive advantage, SNHD has created a self-perpetuating and expanding government agency that is driving legitimate vaccine clinics out of business. It has used the profits from the vaccine program to grow its coffers and expand the size of the organization, which now numbers more than 500 employees.

C. <u>Apexus Is Not Immune from Antitrust Liability as an Instrumentality of the Federal Government</u>

Apexus (at p. 15) contends that it is immune from antitrust liability on the ground that it "enjoys conduct-based immunity from Plaintiff's claims as an instrumentality of the federal government." A

private entity like Apexus is immune from antitrust liability based on the federal instrumentality doctrine in only very limited factual circumstances. In the absence of a federal statute that expressly confers immunity on a private entity, repeals of the antitrust laws by implication are "strongly disfavored, and have only been found in cases of plain repugnancy between the antitrust and regulatory provisions." *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 350-51 (1963). Further, "immunity is provided to a private party acting anti-competitively pursuant to an agreement with a government agency [only] when: (1) the government agency is acting pursuant to a clearly defined policy or program; and (2) the private party is acting at the direction or consent of the government agency." *Byers*, 600 F.3d at 295; *PGMedia*, 51 F.Supp.2d at 401. And even if this two-part test is otherwise satisfied, the private party is still subject to antitrust liability if it had insisted on the inclusion of the anticompetitive restrictions in its agreement with the federal government. *See Otter Tail*, 410 U.S. at 379.

Here, Apexus's federal instrumentality argument fails for several independent reasons. First, it certainly cannot be said that Congress mandated, directed, or compelled Defendants' anticompetitive actions because Congress clearly chose not to impose statutory ceiling prices on the sales of vaccines under the 340B Program as it had done with covered outpatient drugs. Second, the HRSA did not direct or control the alleged price discrimination pursuant to any clear government policy or program. Third, it was Apexus who suggested and insisted on any anticompetitive restrictions in its contract with the HRSA and those restrictions hindered the objectives of the government.

1. Congress Has Not Passed Any Law that Requires Drug Manufacturers to Engage in Price Discrimination with Respect to Vaccine Sales

As noted above, this case does not involve a statutory or regulatory mandate that requires Defendants to engage in the anticompetitive action of selling travel vaccines at below-market prices. Indeed, the prospects of such diversion prompted a Congressional investigation. *See supra*, pp. 5-6.

Congress has clearly and explicitly approved of and authorized price discrimination with respect to "covered outpatient drugs" under the 340B Program, while at the same time choosing to treat vaccines differently by excluding vaccines from the definition of "covered outpatient drugs." *See* 42 U.S.C. § 256b(b)(1); 42 U.S.C. § 1396r-8(k)(2)(B) (defining "covered outpatient drugs" as a biological

product, other than a vaccine . . . ."). It also chose to limit the 340B Program to patients (strictly defined) who are amongst the vulnerable members of the communities, and not businesses such as MGM Resorts.

2. There Is No Clear Agency Policy that Requires Discounts on Vaccines

Just as there is no statute or regulation that requires Defendants to engage in the price discrimination at issue, Apexus also fails to prove as a matter of law that there is any express or "clearly defined [agency] policy or program" that "direct[s]" it or the other Defendants to engage in the alleged anti-competitive conduct. *See Byers*, 600 F.3d at 295.

It is well settled that the federal instrumentality doctrine only immunizes private entities from antitrust liability when the federal government controlled or directed the actions of the private entity. In other words, "[c]onduct is exempt from the antitrust laws only when the regulated entity is required to pursue a particular course of action to comply with an identifiable and specific mandate of the regulatory statute." *Phonetele*, 664 F.2d at 733; *Name.Space*, 202 F.3d at 581 (holding that the applicability of the federal instrumentality doctrine depends "on the extent to which the federal government or its agencies directly own and/or exercise plenary control over the entity in question"). The mere fact that Apexus has entered into a contract with a federal agency (the HHS) that has jurisdiction over its conduct does not mean that it is immune from the antitrust laws.

Here, it is significant that the HRSA agreement expressly requires Apexus to comply with federal law and provides that federal law shall govern "[t]o the extent any term of this Agreement is inconsistent with one or more provisions of any applicable Federal law or regulation." *See* **Ex. D,** at p. 30. Additionally, far from immunizing Apexus from liability for violations of federal law as the agent of the government, the agreement expressly and unambiguously provides that Apexus "shall operate as an independent entity and ***not as an agent of the Federal Government***," that "[n]othing in this Agreement is intended to create an employment or agency relationship," and that Apexus has indemnity obligations to HHS. *Id*. at p. 22, 28, 30 (emphasis added).[17] Further, neither the agreement

[17] Again, it is interesting to note that GSK requested in September 2012 that the participants in the 340B program acknowledge the vaccine (and other) purchases are for their "own use" under

nor the underlying bid submitted by Apexus prove that the HHS or HRSA examined the details of Apexus's proposed vaccine transactions and found it necessary or appropriate to carry out those sales notwithstanding anticompetitive effects.

The self-serving Jimmy Mitchell declaration (Dkt. 158 at 61-68) does not help Apexus – despite the non-disclosed fact that Mr. Mitchell is an employee and/or contractor of Apexus. **Ex. W**. As Mitchell must admit, there is absolutely no Congressional mandate that vaccines be part of the 340B program, and the inclusion of the "value added products" is a voluntary act (Mitchell Decl., ¶ 19). It is difficult to fathom why Apexus did not believe that this Court (or the parties) should know of Mr. Mitchell's employment relationship with Apexus.

V. CONCLUSION

Based on the foregoing, the Court should deny Defendants' motions for summary judgment.

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Respectfully submitted,

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Abbott. This further shows that even GSK recognizes that antitrust laws must be complied with in connection with the sale of vaccines. **Ex. C** [Submitted Under Seal]

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